IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL CASES IDENTIFIED IN EXHIBIT A TO UNDERLYING MOTION**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

AMENDED MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO LIMIT THE OPINIONS AND TESTIMONY OF DR. SALIL KHANDWALA, M.D.

Plaintiffs hereby move this Court to limit the expert testimony proffered by Defendant Ethicon Corp. ("Defendant") expert Dr. Salil Khandwala, M.D. ("Dr. Khandwala") as set forth herein as a General Causation Expert in cases involving the TVT, TVT-O, and TVT-S. Plaintiffs also hereby adopt and incorporate by reference the *Daubert* motion filed with respect to Salil Khandwala, M.D. in Wave 1, [Dkt. 2003 (motion), 2004 (memorandum in support)], related to his opinions on the Prolift or Prolift+M devices as well as the components Gynemesh PS and Ultrapro mesh and respectfully request the Court exclude his testimony for the reasons expressed in the Wave 1 briefing. Plaintiffs hereby seek to further limit certain opinions and testimony proffered by Dr. Khandwala. In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Khandwala is a board-certified physician in Urogynecology and Female Pelvic Medicine and Reconstructive Surgery, and Plaintiffs do not challenge his qualifications as such. *See* Ex. B, General Expert Report (TVT, TVT-O) of Dr. Khandwala at 2-5; Ex. C, General Expert Report (TVT-S) of Dr. Khandwala, at 2-5. However, Dr. Khandwala offers opinions that exceed

the bounds of his qualifications and are founded on insufficient facts and unreliable methodology. Therefore, Dr. Khandwala's opinions on the following topics should be excluded:

- Instructions For Use and warnings for the TVT, TVT-O, and TVT-S;
- FDA regulations, FDA clearance, and compliance with the same;
- Patient brochures for the TVT, TVT-O, and TVT-S;
- Biocompatibility, including degradation, shrinkage, contraction, and particle loss of the TVT, TVT-O, and TVT-S;
- Porosity of the TVT, TVT-O, and TVT-S; and
- Design of the TVT, TVT-O, and TVT-S.

LEGAL STANDARD

The Court acts as a gatekeeper to determine whether an expert's testimony is reliable and relevant. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 598 (1993); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999); Fed. R. Evid. 702. It is the proponent of the expert opinion that bears the burden of establishing its admissibility. *See e.g.*, *Cooper v. Smith & Nephew, Inc.*, 259 F. 3d 194, 199 (4th Cir. 2001). Expert testimony that is unreliable and contrary to law presents a serious risk of confusing the issues and misleading the jury. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.'") (citing *Daubert*, 509 U.S. at 596)). As this Court has noted, "[j]ust because an expert may be 'qualified . . . by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that the expert 'has reliably applied the principles and methods to the facts of this case.'" *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d

589, 612 (S.D. W. Va. 2013). Federal Rules of Evidence govern the admissibility of expert opinion testimony. *Daubert*, 509 U.S. at 587. In a federal court sitting in diversity jurisdiction, the admissibility of expert testimony is a question of and controlled by federal law. *See, e.g.*, *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (quotation omitted). In multidistrict litigation, the law of the transferee circuit governs questions of federal law. *See, e.g.*, *In re Temporomandibular Joint Implants Prod. Liab. Litig.*, 97 F.3d 1050, 1155 (8th Cir. 1996) (citation omitted).

ARGUMENT

I. Dr. Khandwala should be excluded from offering opinions concerning IFUs, warnings, or patient brochures.

Dr. Khandwala is not qualified to opine on the adequacy of the Instructions For Use (IFU), warnings, and patient brochures for the TVT, TVT-O, and TVT-S, and his opinions regarding the IFUs, warnings, and patient brochures are unreliable. Therefore, Dr. Khandwala's opinions on these topics should be excluded.

Dr. Khandwala candidly states in his Report that "I am not a regulatory expert" while simultaneously citing to FDA regulations and statements by the FDA in support of his opinion that the IFUs are adequate. Ex. B at 33; Ex. C at 62. Further, at his deposition, Dr. Khandwala readily admitted that he lacks expertise regarding the information that should, or should not, have been included in the IFUs at issue. When asked if it is important for doctors to have pertinent data in the Instructions for Use, Dr. Khandwala testified, "I'm not a regulatory person as I told you, so I do not know what Ethicon puts in and what they need to put in." Ex. D, Deposition of Dr. Salil Khandwala, at 177:1-10. Dr. Khandwala's lack of expertise renders him unqualified to opine on the adequacy of the IFU for the TVT, TVT-O, and TVT-S. *See Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 582 (S.D. W. Va. 2014) (concluding that expert unqualified to opine

on Obtryx Directions For Use (DFU) after testifying he did not know what information the directions were to include).

Additional testimony by Dr. Khandwala illustrates his lack of qualifications to render an opinion regarding the adequacy of the IFUs and its warnings for the TVT, TVT-O, and TVT-S. In his Reports, Dr. Khandwala cites to FDA regulations and FDA statements, memos, and public health notices. Ex. B at 33; Ex. C at 62. But he admitted at his deposition that he has never worked for the FDA, never consulted for the FDA, and lacks expertise regarding FDA regulations:

> Q: Have you ever worked for the FDA?
>
> A: No, I have not.
>
> Q: Have you ever done any consulting work for the FDA?
>
> A: No, I have not.
>
> Q: Have you ever served as a regulatory consultant?
>
> A: No, I have not.
>
> Q: Have you done any work commenting or helping to draft proposed regulations with the FDA?
>
> A: No, I have not.
>
> Q: Have you done any work advising or consulting on compliance issues with the FDA?
>
> A: No, I have not.
>
> Q: Okay. Do you consider yourself an expert with respect to FDA regulations?
>
> A: No, I do not.
>
> Q: Have you ever done any work drafting warning labels for any kind of medical product?

A: No, I have not.

Q: Okay. And so that would include no warning labels with respect to pelvic mesh products?

A: That is correct.

Ex. D at 57:3-:23.

Further, Dr. Khandwala admitted during his deposition testimony a lack of experience in drafting the Instructions for Use on which he renders his opinion:

Q: Did you draft any portion of the IFU or Instructions For Use on the TVT?

A: I have not.

Q: And did you draft any portion of the IFU with respect to TVT-O?

A: No, I have not.

Q: And I have the same question with respect to the TVT-Secur.

A: No, I have not.

Q: Okay. Did you consult with anyone at Ethicon or did Ethicon consult with you with respect to the Instructions For Use?

A: No.

Id. at 158:24-159:12. Dr. Khandwala's inexperience in drafting IFUs reveals a complete lack of knowledge and experience. S*ee Tyree*, 54 F. Supp. 3d at 584 (concluding expert not qualified to opine on adequacy of Obtryx DFU after admitting at deposition that he had never drafted a DFU). Further, Dr. Khandwala's observations that the IFUs at issue adequately describe risks based on his own practice and experience do not qualify him to render such an opinion without additional expertise in the area of product warnings. *See, e.g.*, *Waltman v. Boston Sci. Corp.*, No. 2:12-cv-691, 2016 WL 3198322, at *17, *18, *21 (S.D. W. Va. June 8, 2016) (excluding experts as unqualified to render opinions on adequacy of DFU).

Additionally, Dr. Khandwala wholly lacks experience and expertise related to warnings, which disqualifies him from opining on the adequacy of the IFUs. Dr. Khandwala has never drafted a warning, as he testified at his deposition:

> Q: Have you ever done any work drafting warning labels for any kind of medical product?
>
> A: No, I have not.
>
> Q: Okay. And so that would include no warning labels with respect to pelvic mesh products?
>
> A: That is correct.

Ex. D at 57:18-23. Dr. Khandwala lacks the knowledge, skill, experience, training, or education to opine as to the adequacy of the IFU for the TVT, TVT-O, and TVT-S. *See* Fed. R. Evid. 702.

This same lack of qualification to render an opinion regarding the adequacy of the IFUs and warnings applies to the patient brochures for the TVT, TVT-O, and TVT-S. In his Reports, Dr. Khandwala provides a brief, three-sentence statement that he has reviewed the patient brochures "and the adequacy and appropriateness of the brochure, as well as applicable marketing documents." Ex. B at 35; Ex. C at 63. It is unclear if Dr. Khandwala intends to offer an opinion, based on this review of the patient brochure, of the adequacy of the patient brochure. If so, at his deposition, Dr. Khandwala stated—as he did when questioned about his qualifications to opine on his expertise related to IFUs—that he has no experience creating or drafting patient brochures:

> Q: Did you draft any patient brochures regarding Ethicon's midurethral slings?
>
> A: No, I have not.
>
> Q: Did Ethicon consult with you with respect to the patient brochures for its midurethral slings?

A: No, they did not.

Ex. D at 159:13-:18. Dr. Khandwala has no relevant skills, knowledge, or expertise regarding patient brochures and is therefore not qualified to opine on the adequacy of patient brochures.

Even if Dr. Khandwala was qualified to testify as to the adequacy of the IFUs or patient brochures (which he is not), his opinions regarding the IFUs and patient brochures remain inadmissible because they are not the product of a reliable methodology. First, Dr. Khandwala relies on FDA regulations and statements to form his opinion regarding the IFUs despite a complete lack of background or expertise related to the FDA. Second, Dr. Khandwala relies on sweeping statements related to medical literature, attendance at medical conferences, and the TVT professional education system as the basis for his opinion that the IFUs are adequate. *See* Ex. B at 32-34; Ex. C at 61-65. Such generalized statements do not provide a scientifically valid methodology for reaching his opinion that the IFUs or patient brochures provide adequate warning. *See Westberry*, 178 F.3d at 260 (stating that expert testimony is admissible when it concerns scientific or specialized knowledge that "is supported by adequate validation to render it trustworthy").

Neither Dr. Khandwala's Reports nor his sworn testimony set forth any specific analysis or study of the IFUs. Indeed, Dr. Khandwala essentially conceded that the IFU for the TVT-S was inadequate because physicians needed to supplement the instructions with additional documents to clarify the IFU. Ex. D at 113:12-114:11.

Notwithstanding, Dr. Khandwala opines that the IFUs are adequate because he personally hasn't seen the adverse events that were not included in the relevant and earlier versions of the IFUs. *See id.* at 146:1-147:1. However, Dr. Khandwala admits that his experience in treating women who have had adverse events subsequent to the mesh implant is

extremely limited and he has only performed a handful of revision procedures. *See id.* at 147:2-14. Dr. Khandwala also acknowledges that the experience of the implanter is significant and plays an important role in the success, as well as the potential adverse events, experienced by any particular patient. *See id.* at 146:1-22; 154:16-155:16.[1] Dr. Khandwala provides no specific objective or scientific methodology to support his opinion that the IFUs were adequate. *See* Ex. B at 34; Ex. C at 65. Because Dr. Khandwala is unqualified to opine on this topic and because his opinions lack any reliable scientific methodology, his opinions related to the IFUs and patient brochures for the TVT, TVT-O, and TVT-S should be excluded.

II. Dr. Khandwala's opinions on FDA regulations, FDA clearance, and compliance with the same must be excluded.

Dr. Khandwala is not qualified to opine on FDA regulations, the FDA's 510(k) process, or compliance with the same. Therefore, Dr. Khandwala's opinions relating to FDA regulations, the 510(k) process, and compliance with the same should be excluded.

Dr. Khandwala admits in his Reports that "I am not a regulatory expert" in addition to testifying at his deposition that "I'm not a regulatory person as I told you." Ex. B at 33; Ex. C at 62; Ex. D, at 177:1-10. Such admissions alone render Dr. Khandwala's unqualified to opine on FDA regulations and the 510(k) process. Further, Dr. Khandwala admitted at his deposition that he has never worked for the FDA, never consulted for the FDA, and lacks expertise regarding FDA regulations. Ex. D at 57:3-:23. Additionally, Dr. Khandwala testified that he has no experience related to the 510(k) process.

> Q: Okay. Have you participated in submissions or assembly of materials for a 510(k) submission?

[1] It is important to note that while Dr. Khandwala testified that the experience of the physicians played a significant role in the success of the implant, as well as in the potential adverse event rates, and that additional documents were necessary to expand upon and/or clarify the IFUs, he did not feel that doctors had breached the standard of care if a patient suffered from adverse events following the implant. Ex. D at 131:23-134:3.

A: No, I have not.

Q: And you have not authored any peer-reviewed articles with respect to 510(k) submissions?

A: That is correct.

Id. at 68:11-16. Therefore, because Dr. Khandwala wholly lacks expertise relating to FDA regulations and the 510(k) process, his opinions relating to FDA regulations, the 510(k) process, and the compliance with the same should be excluded. As this Court has repeatedly held, the parties may not submit any evidence, including expert opinions, regarding the FDA 510(k) process. *See, e.g., Tyree*, 54 F. Supp. 3d at 584 (stating that expert opinions on FDA 510(k) process were inadmissible); *see also Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *36-37 (S.D. W. Va. Sept. 29, 2014) (concluding that parties may not present evidence regarding the 510(k) process because the process does not relate to safety or efficacy). Dr. Khandwala's opinions relating to FDA regulations, the 510(k) process, and compliance with the same should likewise be excluded.

III. Dr. Khandwala's opinions on biomaterials issues, including degradation, particle loss, contraction, and shrinkage must be excluded.

Dr. Khandwala is not qualified to offer opinions regarding the properties of polypropylene mesh used in the TVT, TVT-O, and TVT-S, in particular his opinions that the devices do not degrade, shrink, or contract and that particle loss of the mesh does not occur. Dr. Khandwala is not a biomaterials expert, and he conceded at his deposition that he is not a pathologist or toxicologist:

Q: Do you have – you're not a pathologist, are you?

A: I am not.

> Q: Okay. And so you don't have any certifications with respect to pathology?
>
> A: I can see slides. As a part of gynecology residency, we do a pathology rotation. So we can see slides and understand how to read slides, but I'm not a certified pathologist.
>
> Q: Okay. And you have not previously served as an expert specific to issues on pathology?
>
> A: That is correct.
>
> Q: Okay. And you are not a toxicologist, are you, Doctor?
>
> A: I am not.
>
> Q: Okay. And you have not previously served as an expert on issues specific to toxicology?
>
> A: That is correct.

Ex. D at 58:01-:18. In light of these concessions alone, Dr. Khandwala should be excluded from opining on the properties of polypropylene mesh. Additional testimony supports excluding his biomaterials opinions as Dr. Khandwala admitted that he has never conducted bench testing on explanted mesh or polypropylene itself:

> Q: Have you ever conducted any studies on polymers?
>
> A: No.
>
> Q: Have you authored any peer-reviewed articles specific to polymers?
>
> A: No, I have not.
>
> Q: Have you done any bench research specific to polypropylene?
>
> A: No, I have not.

Id. at 70:9-17. Dr. Khandwala further testified that he has never performed a microscopic evaluation of explanted mesh:

> Q: Okay. And when you conduct those explants, do you do any sort of microscopic evaluation of the mesh that you remove?
>
> A: I do not, but sometimes – I am not sure if I've done that, but I may have sent it for pathology.
>
> Q: So you send it on to somebody else to handle the pathology, is that correct?
>
> A: If I did that, yes.
>
> Q: Okay. Do you have a degree in epidemiology?
>
> A: I do not.
>
> Q: Is it fair to say you would not call yourself an expert on epidemiology?
>
> Q: Yes.

Id. at 71:15-72:3.

And, in fact, Dr. Khandwala concedes not only that he has not tested explanted mesh for degradation, but that he does not study effects that he does not already believe exist:

> Q: Okay. And you haven't tested any mesh that you have removed from patients for degradation, have you?
>
> A: I don't believe the mesh degrades, but I have not done any of that.
>
> Q: So you haven't done any testing on that?
>
> A: No.

Id. at 141:15-20. Additionally, Dr. Khandwala has not conducted any testing of explanted mesh to analyze for shrinkage.

> Q: And with respect to slings specifically, you haven't done any studies on the mesh itself once it's been removed, even partially removed, in terms of shrinkage of the mesh or any alterations to the biomechanical properties of that mesh?
>
> A: I don't know how one can do shrinkage assessments in the lab, but biomechanical, I have not done any.

Id. at 144:22-145:4. Further, Dr. Khandwala has not published on the topic of degradation:

> Q: Have you conducted any studies with respect to degradation of pelvic mesh?
>
> A: No, I have not.
>
> Q: And have you published any studies specific or, I'm sorry, published any articles specific to degradation of pelvic mesh?
>
> A: No, I have not.

Id. at 66:23-67:5. Likewise, Dr. Khandwala has not studied mesh explanted by others.

> Q: Okay. And you haven't done any specific studies on TVT or TVT-O that other doctors have removed?
>
> A: No.

Id. at 148:12-14. Because Dr. Khandwala lacks expertise in the area of biocompatibility, including shrinkage, contraction, degradation, and particle loss, his opinions concerning these topics must be excluded.

Even if Dr. Khandwala was qualified to testify as to degradation, contraction, shrinkage, and particle loss (which he is not), his opinions regarding degradation, contraction, shrinkage, and particle loss remain inadmissible because they are not the product of a reliable methodology. This Court previously has looked to the expert's ability to provide reasoned explanations for his opinions on the physical properties of polypropylene mesh and has determined that when these opinions are only general in nature, and based on the gross examination of mesh, there is no reliable scientific methodology for such opinions. *See Tyree*, 54 F. Supp. 3d at 580-81 (excluding expert's opinions on physical properties of mesh, including degradation, when his opinions were based only on his general gross examination of explanted mesh, without performing any kind of testing or measurements). In his Reports Dr. Khandwala states that he has not "seen any migrating particles or mesh that was degraded based on an observation at

surgery." Ex. B at 36; Ex. C at 67. But Dr. Khandwala admitted at his deposition that he has not tested explanted mesh, which fails to meet the threshold of reliability:

> Q: And you have not analyzed any of the mesh material that has been removed from women in terms of any degradation or change in consistency of that mesh from a pathologic point of view, have you?
>
> A: I have not analyzed mesh.

Ex. D at 97:16-20.

> Q: Okay. And you haven't tested any mesh that you have removed from patients for degradation, have you?
>
> A: I don't believe the mesh degrades, but I have not done any of that.
>
> Q: So you haven't done any testing on that?
>
> A: No.

Id. at 141:15-20.

Dr. Khandwala also acknowledged that his experience in the removal, or even partial removal, of polypropylene mesh is extremely limited. Indeed, Dr. Khandwala testified that he has only removed polypropylene mesh on approximately 25 occasions and only seven or eight of these would relate directly to polypropylene mesh used in stress urinary incontinence procedures (*e.g.*, the TVT, TVT-O, or the TVT-S). *See id.* at 147:2-14.

Dr. Khandwala improperly bases his opinion regarding degradation on the very type of gross examination that this Court has held to be insufficient under *Daubert*. *Tyree*, 54 F. Supp. 3d at 580-81. Further, Dr. Khandwala has never studied or tested mesh to analyze mesh shrinkage, revealing the same inadequate and unreliable methodology:

> Q: And with respect to slings specifically, you haven't done any studies on the mesh itself once it's been removed, even partially removed, in terms of shrinkage of the mesh or any alterations to the biomechanical properties of that mesh?

> A: I don't know how one can do shrinkage assessments in the lab, but biomechanical, I have not done any.

Ex. D at 144:22-145:4. Dr. Khandwala's testimony that he has not conducted a microscopic evaluation of explanted mesh further demonstrates the lack of reliability of his opinions on degradation, contraction, shrinkage, and particle loss:

> Q: Okay. And when you conduct those explants, do you do any sort of microscopic evaluation of the mesh that you remove?
>
> A: I do not, but sometimes – I am not sure if I've done that, but I may have sent it for pathology.
>
> Q: So you send it on to somebody else to handle the pathology, is that correct?
>
> A: If I did that, yes.

Id. at 71:15-:22. Dr. Khandwala's failure to microscopically evaluate explanted mesh renders his opinions on degradation, shrinkage, contraction, and particle loss unreliable. *See Winebarger v. Boston Sci. Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *35 (S.D. W. Va. Apr. 24, 2015) (concluding expert's methodology regarding opinions on physical properties of polypropylene mesh unreliable where expert never measured mesh product under a microscope). Therefore, Dr. Khandwala's opinions regarding degradation, shrinkage, contraction, and particle loss should be excluded.

IV. Dr. Khandwala should be excluded from offering opinions concerning the porosity of the TVT, TVT-O, and TVT-S.

Dr. Khandwala is not qualified to proffer an opinion regarding the porosity of TVT, TVT-O, and TVT-S, and the opinions he has proffered are unreliable and must be excluded. Dr. Khandwala lacks expertise relating to the porosity of mesh. He has not studied the issue of porosity, nor has he published on the topic:

> Q: Have you conducted any studies that are specific to the porosity issues?

A: No, I have not.

Q: Have you published any peer-reviewed literature with respect to, specifically with respect to porosity of pelvic mesh?

A: No, I have not.

Ex. D at 66:16-:22.

Q: Have you conducted any studies specific to the flexibility or stiffness of pelvic mesh?

A: No, I have not.

Q: Have you published any articles specific to flexibility or stiffness of pelvic mesh?

A: I have not specifically stated or published a paper on flexibility or as you mentioned porosity.

Id. at 67:6-12.

Further, Dr. Khandwala's opinions on the porosity and qualities of Ethicon mesh are based on insufficient data. *Id.* at 145:18-24. Accordingly, Dr. Khandwala's opinions regarding the porosity of the TVT, TVT-O, and TVT-S should be excluded because he lacks expertise on the topic and, in addition, because his opinions are unsupported and unreliable.

V. Dr. Khandwala should be excluded from offering opinions concerning the design of the TVT, TVT-O, and TVT-S

Dr. Khandwala is not qualified to opine on the design of the TVT, TVT-O, and TVT-S, and his opinions regarding the design of the TVT, TVT-O, and TVT-S are unreliable. Therefore, Dr. Khandwala's opinions relating to the design of the TVT, TVT-O, and TVT-S should be excluded.

Dr. Khandwala's deposition testimony reveals that he fully lacks any experience in designing any of the relevant devices:

> Q: Okay. And with respect to the design of Ethicon's synthetic midurethral sling, you did not participate in the design of those products, is that correct?
>
> A: That is correct.
>
> Q: And you did not participate in the design controls with respect to those products? That is correct.

Ex. D at 156:2-:8.

> Q: And have you participated in any meetings with Ethicon regarding the design of its midurethral sling products?
>
> A: I think, I believe by the time the TVT-Secur, when we initially started the clinical trial, the design was already established, so I was not involved in the design of the TVT-Secur.
>
> Q: Have you authored or contributed to any of Ethicon's failure analysis documents?
>
> A: No, I have not.

Id. at 157:5-11, 157:21-23.

Dr. Khandwala stated at his deposition that he considered himself an expert in the design of synthetic midurethral slings, but his testimony clarified that any design experience goes to technique, not the device itself.

> Q: And you do not consider yourself an expert on the design of synthetic midurethral slings, do you?
>
> A: I'm sorry.
>
> Mr. Walker: Object to form.
>
> A: Actually, I do. That's part of the reason why I'm working on this particular patent.
>
> Q: Okay. And the patent, did you say that had to do with the implant technique or the mesh itself?
>
> A: It's more the implant technique and technique itself.

Id. at 154:4-15. Dr. Khandwala's lack of experience relating to the design of the TVT, TVT-O, and TVT-S renders his opinions on design inadmissible. *See Tyree*, 54 F. Supp. 3d at 581 (excluding expert's opinion on design of Obtryx after expert admitted he lacked experience with sling design); *see also Robbins v. Boston Sci. Corp.*, No. 2:12-CV-01413, 2016 WL 3189248, at *22 (S.D.W. Va. June 7, 2016) (excluding expert's opinion regarding mesh design where expert testified he had not designed any POP products and rejecting argument that expert had sufficient experience with pelvic floor kits to opine as to device design). Further, Dr. Khandwala's only knowledge related to design standards for the product at issue was derived from reading certain materials:

> Q: And do you have any knowledge regarding Ethicon's internal standards with respect to their design controls for those products?
>
> A: Yes, I do.
>
> Q: Okay. And what is your knowledge regarding Ethicon's standards?
>
> A: I have read several documents that have gone over exhaustive studies for right from the Prolene suture and how it was studied to the mesh, the sling, and to the instruments, the needle that was placed for the TVT-Secur, for example, and the validation criteria that were done, the clinical trials that were done, whether it was a sheep model or ultimately the human model. So I've reviewed all that. And on the review of the literature, my opinion is that there is extensive research and work done in validation of the device and the instruments.
> Q: So that's based on your review of literature that other people have authored?
>
> A: Yes.

Ex. D at 156:9-157:4. However, Dr. Khandwala's cursory review of these documents alone is insufficient to render any opinions he may have on the design of the mesh reliable. Indeed, there are more than 2,200 materials listed on Dr. Khandwala's reliance list—not including any case-specific medical records. Dr. Khandwala testified that he has spent approximately 72 hours

reviewing these materials. *See* Ex. D at 11:15-14:14, 44:18-45:4. Thus, on average, Dr. Khandwala could not have spent more than two minutes reviewing each of the documents on his reliance list. This cannot form the basis of a reliable opinion.

Therefore, Dr. Khandwala's opinions regarding the design of the TVT, TVT-O, and TVT-S should be excluded because he lacks the relevant skills, knowledge, or expertise and is therefore not qualified to opine on design issues. Further, any opinions Dr. Khandwala may have regarding the design of the mesh is unreliable.

CONCLUSION

For each of the reasons set forth above, the Plaintiffs respectfully request that this Court preclude Dr. Khandwala from offering opinions on the following topics:

- Instructions For Use and warnings for the TVT, TVT-O, and TVT-S;
- FDA regulations, FDA clearance, and compliance with the same;
- Patient brochures for the TVT, TVT-O, and TVT-S;
- Biocompatibility, including degradation, shrinkage, contraction, and particle loss of the TVT, TVT-O, and TVT-S;
- Porosity of the TVT, TVT-O, and TVT-S; and
- Design of the TVT, TVT-O, and TVT-S.

Dated: July 25, 2016

LOCKRIDGE GRINDAL NAUEN, P.L.L.P.

By: /s/Yvonne M. Flaherty

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CERTIFICATE OF SERVICE

I hereby certify that on July 25, 2016, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

By: /s/ Yvonne M. Flaherty